

Reference Number: NC10067-AC Issuance Date: December 17, 2012

Version: Revision

VIA: USPS Certified Mail December 17, 2012

Shipping Event: 1st

Wake Forest University c/o Janice Wagner, D.V.M., Ph.D Institutional Officer Medical Center Boulevard Winston Salem, NC 27157 James Reid Morgan 214 Reynolda Hall, Wake Forest University 1834 Wake Forest Road Winston Salem, NC 27106

CITATION AND NOTIFICATION OF PENALTY

We believe that you violated the Animal Welfare Act (7 U.S.C. § 2131 et seq.) (AWA), as described below.

Date of Violation: May 13, 2009

9 C.F.R. § **3.81(c)(2)** Environment enhancement to promote psychological well-being of non-human primates: (c) Special Considerations (2) Those that show signs of being in psychological distress through behavior or appearance.

Wake Forest University (WFU) failed to document a written plan for special attention for two non-human primates who showed signs of hair picking, alopecia, and some abnormal behavior.

Date of Violation: June 15, 2010

9 C.F.R. § 2.31(c)(7) The IACUC shall review and approve, require modification in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.

WFU failed to obtain IACUC approval before implementing a significant change in post-surgical care, and hematomas developed on the ears of 3 rabbits. WFU also failed to obtain IACUC approval before implementing significant changes in a protocol, including changes regarding the number of animals used, glucose monitoring, and the insulin dose and route. The researcher, without approval from the IACUC, exceeded the number of rabbits that were approved to be pharmaceutically induced to become diabetic. The mortality rate for this group was higher than the expected rate.

Reference Number: NC10067-AC Issuance Date: December 17, 2012

Version: Revision

Date of Violation: June 15, 2010

9 C.F.R. § **2.31(d)(1)(i)** In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC will confirm that the principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animal and has provided a written narrative describing the methods used to determine that alternatives were not available.

WFU initially approved a protocol to require glucose monitoring once a month after the Alloxan injection to induce diabetes. This level of monitoring was insufficient to avoid or minimize discomfort, distress, or possible death due to hypoglycemia.

Date of Violation: June 15, 2010

9 C.F.R. § **2.32(a)** It shall be the responsibility of the research facility to ensure that all...personnel involved in animal care, treatment and use are qualified to perform their duties.

WFU failed to ensure that personnel were qualified to care for, treat, and use animals in performing their duties. A researcher failed to use an AVMA-approved method for emergency euthanasia of a rabbit. Staff administered improper doses of insulin because they were unfamiliar with measuring insulin and the use of insulin syringes, which resulted in rabbits receiving a higher dose. Other personnel did not have adequate experience monitoring diabetic animals and failed to monitor glucose levels.

Date of Violation: June 15, 2010

9 C.F.R. § 2.35(a)(1) The research facility shall maintain minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations.

WFU failed to maintain complete minutes of IACUC meetings by failing to include Committee pre-meeting and post-meeting deliberations for some IACUC meetings.

Date of Violation: January 13, 2011

9 C.F.R. § **2.32(a)** It shall be the responsibility of the research facility to ensure that all...personnel involved in animal care, treatment and use are qualified to perform their duties.

WFU failed to ensure that personnel were qualified to care for, treat, and use animals in performing their duties. An investigator was observed using inadequate sterile technique during a procedure. Staff also had issues taking accurate blood pressure readings for animals.

Reference Number: NC10067-AC Issuance Date: December 17, 2012

Version: Revision

Date of Violation: January 13, 2011

9 C.F.R. § 3.84(c) Premises must be kept clean and in good repair.

WFU failed to repair an overhead ventilation duct in Clean Cage Wash Room, which leaked over an area where clean cage racks were stored.

Date of Violation: June 28, 2012

9 C.F.R. § **3.75(a)** Housing facilities for nonhuman primates must be designed and constructed so that they are structurally sound for the species of nonhuman primates housed in them. They must be kept in good repair, and they must protect the animals from injury, contain the animals securely, and restrict other animals from entering.

WFU failed to maintain housing facilities for nonhuman primates that contained the animals securely. One female cynomolgus macaque escaped from the facility during enclosure cleaning on June 28, 2012. The macaque escaped by manipulating a latch, and was not recovered until July 10, 2012.

The penalty for the alleged violation(s) described above is \$35,464.